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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,370	07/06/2000	Robert C. Fahey	UCSD1130-1	6677

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[REDACTED] EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/14/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/530,370	FAHEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26August2002.

2a) This action is **FINAL**.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-40 and 42-50 is/are pending in the application.

4a) Of the above claim(s) 12-39 and 43-45 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-11,40,42 and 46-50 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-40,42-50 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

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## **DETAILED ACTION**

1. Applicants' Response to Office Action, received 26August2002, paper#10, is acknowledged. Claims 41 has been canceled without prejudice. Claims 1, 2, 4, 7, 8, 9, 40, 42, and 46 have been amended.
2. Claims 1-40 and 42-50 are pending. Claims 12-39 and 43-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(Office Action, mailed 4April2002, paper#8).
3. Claims 1-11, 40, 42, and 46-50 are under consideration.

### **Rejections Moot/Withdrawn**

4. The rejection of claim 41 under 35 U.S.C. 112, first paragraph, scope of enablement, is moot in light of the cancellation of the claim.
5. The rejection of claims 1-11, 40, 42, and 46-50 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in light of the amendment of the claims.

Applicants argue that the examples and figure 4 in the specification disclose that an antibody that specifically binds to either mycothiol or to precursors of mycothiol can be obtained using the procedures described in the specification. Figure 4 shows that the same antibody that binds to mycothiol binds to the thiol-containing molecule NacCysGlcN, which is a component of mycothiol.

The examiner has considered applicants' argument, but does not find it persuasive. As stated in the original rejection, the specification teaches an antibody which binds to whole MSH

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and NacCysGlyN, but does not bind to other precursors. Thus, the guidance in the specification is insufficient for enablement of providing antibodies which specifically bind to precursors.

However, the newly amended claims no longer recite that the reagent detects precursors, but now recite that the reagent is thiol-selective and that a purified antibody specifically binds to mycothiol or a thiol-containing mycothiol component. Thus, the amendment of the claims obviates the original rejection.

6. The rejection of claims 1-3, 7, and 8 under 35 U.S.C. 102(b) as being anticipated by Newton et al (*Journal of Bacteriology*, 178(7):1990-1995, April 1996), is withdrawn in light of the claim amendments.

Applicants argue that the amendment of the claims to recite that the method requires the presence of a purified antibody that specifically binds to mycothiol or a thiol-containing mycothiol component obviates the rejection because Newton et al does not teach such antibodies.

The examiner has considered applicants' argument, and in light of the newly amended claims, finds it persuasive.

7. The rejection of claims 40 and 42 under 35 U.S.C. 103(a) as being unpatentable over Newton et al (*Journal of Bacteriology*, 178(7):1990-1995, April 1996) is withdrawn in light of the amendment of the claims.

Applicants argue that the amendment of the claims to recite that the kits comprise a purified antibody that specifically binds to mycothiol or a thiol-containing mycothiol component obviates the rejection because Newton et al does not teach such antibodies.

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The examiner has considered applicants' argument, and in light of the newly amended claims, finds it persuasive.

8. The objection to claim 2 is withdrawn in light of the amendment of the claim.

#### **Claim Rejections - 35 USC § 112**

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-8, and 46-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting mycothiol by detecting complexes of mycothiol and an antibody that specifically binds to mycothiol, does not reasonably provide enablement for a method of detecting a member of the taxa actinomycetes comprising detecting reaction of a thiol-selective reagent with a thiol. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

One of the embodiments encompassed by the newly amended claims is incubating a sample with a thiol-selective reagent and an antibody that specifically binds to mycothiol or a

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thiol-containing mycothiol component. Following sufficient time for said reagent **or** (emphasis added) said antibody to react with mycothiol or thiol-containing mycothiol component, one detects the reaction of said reagent **or** (emphasis added) said antibody with said thiol, thus indicating the presence of a member of the taxa actinomycetes.

While the specification teaches a method of detecting actinomycetes by utilizing both a thiol-selective reagent **and** (emphasis added) a mycothiol specific polyclonal antibody, the specification does not teach how to distinguish mycothiol from any and all other thiol-containing compounds using **only** the said thiol-selective reagent. Step b of claim 1 recites that one can detect actinomycetes by detecting the reaction of said reagent **or** said antibody. Thus, one need only have a reaction of the thiol-selective reagent to fulfill the claim requirements. However, the thiol-selective reagents taught by the instant specification are not selective only for mycothiol, but any/all thiol containing compounds, and therefore, does not distinguish between actinomycetes and any other microorganism or cell containing thiols.

**12.** Claims 5, 10, 40, and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 5 and 10 are directed to monoclonal antibodies. Claims 40 and 42 encompass both monoclonal as well as polyclonal antibodies. The instant specification provides only examples of one polyclonal antibody. Therefor, the specification does not reasonably convey to

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one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., monoclonal antibodies.

### **Claim Rejections - 35 USC § 101**

**13.** 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**14.** Claims 9-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. .

The claims are directed to “an antibody” without any requirements that the antibody be isolated or purified. Therefore, the claims read on a product of nature which may be formed following exposure of a host to a mycothiol containing microorganism.

### **Conclusion**

**15.** No claims are allowed.

**16.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P. SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

November 13, 2002